

## REMARKS

### **I. Status of the Claims**

Claims 1-30 and 35-38 are pending in the application. Claims 35-37 stand withdrawn. Claims 1-30 and 38 have thus been examined as stand and rejected under 35 U.S.C. §102 and §103 over U.S. Patent 6,152,964 (“the ‘964 patent”), optionally in combination with Long *et al.* The specific grounds for rejection, and applicants’ response thereto, are set out in detail below.

### **II. Telephonic Interview**

Applicants wish to thank Examiner Witz for the courtesy of a telephonic interview held on January 28, 2004. Though agreement was not reached, applicants believe the interview was helpful in clarifying the remaining issues.

### **III. Rejection Under 35 U.S.C. §102 Over U.S. Patent 6,152,964**

Claims 19, 22-28 and 38 stand rejected under §102(a) or (e) over the ‘964 patent. The ‘964 patent is said to disclose “globular structures” or “nodules” which, in the absence of evidence to the contrary, are believed to be the same as the instantly claimed bone spheroids. Applicants once again traverse.

Applicants have previously provided declaratory submissions from the inventor and another expert opining that the nodules described in the ‘964 patent are not the same as the bone spheroids of the claimed invention. The reasons for this conclusion will not be repeated here in their entirety, but rather, applicants wish to focus on a single issue raised by the inventor, Dr. Michael Long. In paragraph 5 of his declaration. Dr. Long noted that FIGS. 1 and 4 of the ‘964 patent show scanning electron micrographs of the “globular structures” that are proposed to anticipate the bone spheroids of the present invention. In the examples, these globules are said to

be 0.2-1  $\mu\text{m}$  and 1-2  $\mu\text{m}$  in diameter, respectively. Bone cells and precursors can range in size from 8-70  $\mu\text{m}$  in diameter. See specification at page 15, lines 1-4. ***Thus, by definition, these globules are acellular and cannot anticipate the present claims to bone cell spheroids.***

Nonetheless, the present claims now have been amended to recite that the claimed bone cell spheroids contain between about 3000 and 100,000 cells (support for amendment deriving from page 10, line 10 of the specification). Thus, even accounting for the three dimensional nature of bone cell spheroids, these structures are at least two orders of magnitude larger than the globules of the '964 patent.

In further support of the foregoing, applicants submit the attached declaration of Dr. Michael Long. In Dr. Long's declaration, he provides factual bases for drawing the conclusions on bone cell and bone spheroid size, as set forth above. Thus, it is respectfully submitted that applicants have set forth a reasonable basis for their position that the '964 patent ***cannot*** describe bone spheroids of the present invention.

In light of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. Rejections Under 35 U.S.C. §103 Over the '964 Patent, Optionally With Long *et al.***

Claims 1-9, 17 and 18 stand rejected under §103 over the '964 patent. Claims 10-16, 20-22, 25, 29 and 30 stand rejected under §103 over the '964 patent in view of Long *et al.* Applicants traverse.

Both of these rejections are premised on the supposition that the '964 patent teaches bone cell spheroids as claimed here. As discussed above, this is ***not*** the case, and the Long *et al.* reference similarly fails to disclose anything like the bone cell spheroids of the present

application. As such, these rejection too fail as the cited art does not disclose each limitation of the claimed invention.

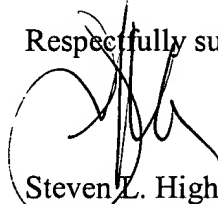
In light of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection.

**V. Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned at the telephone number listed below with any questions, comments or suggestions relating to the referenced patent application.

Please date stamp and return the enclosed postcard as evidence of receipt.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-3184

Date: March 15, 2004